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APPLICATION NO.	FILING DATE	U.S. NAMED INVENTOR	CLASSIFICATION	CLASSIFICATION
09/620,038	07/20/2000	Udo Hoss	R01D06001S	01S

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EXAMINER

GITOMER, RALPH J

ARTICLE PAPER NUMBER

DATE MAILED 03/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/620,038

Applicant(s)
Hoss et al.

Examiner
Ralph Gitomer

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 2, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-50 and 68-79 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-50 and 68-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____ 6) ☐ Other: _____

The RCE request received 1/2/03 and the amendment received 11/14/02 have been entered and claims 23-50, 68-79 are currently pending in this application.

5 The rejection under 35 USC 103 over Pfeiffer (6,091,976) is maintained.

Applicant's arguments filed 11/14/02 have been fully considered but they are not persuasive.

10 Applicants argue that Pfeiffer teaches setting an initial glucose concentration in the perfusion solution which is maintained unchanged during testing. The predetermined glucose baseline is set in other words. Whereas the presently claimed invention includes adjusting the starting content of glucose in the perfusate in accordance with a command variable corresponding
15 with the glucose concentration of the body fluid.

20 It is the examiner's position that ss presently claimed, this point of novelty feature is so vague as to not be possible to distinguish from Pfeiffer. Pfeiffer teaches in the abstract, continuously detected signals for monitoring tissue glucose concentrations. The predetermined concentration is set within
25 the physiological range depending on the tissue glucose concentration as described in column 1 last paragraph. The function of the teaching of Pfeiffer and that presently claimed appears identical. See the present specification page 2 last full paragraph.

Claims 23-50, 68-79 are rejected under 35 U.S.C. § 112,
second paragraph, as being indefinite for failing to particularly
point out and distinctly claim the subject matter which applicant
regards as the invention. Each of the following applies in all
5 occurrences.

In claim 23 line 8, ~~the measuring cell~~ lacks antecedent
basis. In claim 23 the obtaining measurement signals does not
state how the signals are obtained nor from what. And the next
step, ~~measuring the measurement signals~~ is not understood.
10 There are no steps presented to accomplish the last determining
step. Claim 23 as amended still does not have a step which
determines glucose concentration. Note there may be some
confusion between content and concentration in the claims. The
determining of the starting content of glucose in claims 25 and
15 26 remains indefinite.

Regarding new claims 68-79, in claim 68 ~~in alternating
successive transport and dialysis intervals~~ is not understood.
Further, ~~measuring measurement signals~~ is unclear because no
measurement signals have been obtained and what they might be
20 measured for is not seen. And how can one adjust the starting
content of glucose if one must first measure the glucose
concentration? If the starting content of glucose is set
according to a command of some sort, how can the momentary
starting content of glucose be a measure of glucose content of
25 the body fluid? If a feedback is intended to adjust the starting

glucose concentration, it is not found in the claims as presented. Claim 76 contains many values but how they are obtained is not found in the claims.

5 The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the
15 examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to
20 patent application information 7 days per week, or for filing applications electronically, please visit our website at

Serial No. 09/620,038
Art Unit 1651

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Center for more information.

Ralph Gitomer
Primary Examiner
Group 1651

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